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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,015	01/14/2004	Axel Riedel	1/1443US	3296

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,015	RIEDEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 8-35 are presented for examination.

Applicant's Amendment filed September 19, 2006 has been received and entered into the present application.

Claims 1 and 8-35 remain pending and are under examination. Claims 2-7 have been cancelled and claim 1 is amended.

Applicant's arguments, filed September 19, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8-17 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of hypertension combined with hyperlipidemia or atherosclerosis, asthma, bronchitis, interstitial lung disease, type 2 diabetes mellitus, prediabetes, metabolic syndrome, insulin resistance or hypertensive insulin resistance, does not reasonably provide enablement for the prevention of the same, for the reasons set forth at pages 4-14 of the previous Office Action dated March 30, 2006, of which said reasons are herein incorporated by reference.

Applicant states that present claims 1-35 were subject to the rejection under the enablement requirement of 35 U.S.C. 112, first paragraph. Applicant further states that they disagree with the conclusion that prevention requires absolute success and assert that this is an unreasonable interpretation

of the meaning of the term "prevention" and is accordingly improper. Applicant relies upon the decision of *Ex parte Cho* in support of their position that the activity of a compound or composition in treating a condition would also be expected to be effective in preventing the same, if they were administered before the onset of such a condition.

First, it is noted that the present rejection was never set forth as applying to composition claims 18-35. Please reference page 4 of the previous Office Action. It is assumed that this is a typographical error by Applicant. Any remarks by Applicant directed to the alleged lack of enablement rejection over the claims directed to a pharmaceutical composition will not be further treated herein since the Examiner never set forth such a rejection.

Second, it is well settled in patent law that interpretation of the claims during examination must be given their broadest and most reasonable interpretation consistent with the disclosure. Please reference MPEP §2111, which states, "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard: The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 [70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.' 37 CFR 1.75(d)(1). 415 F.3d at 1316, 75 USPQ2d at 1329. See also *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during

prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).'"

Consequently, though Applicant disagrees with the Examiner's interpretation of the word "prevention", the Examiner is attributing the broadest, most reasonable interpretation of this term in the art to the claims in accordance with the MPEP at §2111. While a interpretation contrary to that defined in Applicant's specification would be improper and contrary to the teachings of the MPEP, Applicant is reminded that the instant disclosure fails to define the term "prevention" in the manner that Applicant apparently intends for it to be interpreted. Thus, while Applicant is most certainly entitled to a different opinion than that of the Examiner, the Examiner's interpretation of the term "prevention" is in keeping with the standard and teachings of the MPEP at §2111 and is, therefore, considered a valid interpretation of the claims.

Further, Applicant's reliance upon the decision rendered in *Ex Parte Cho* has been carefully considered, but is not persuasive. It is noted that each case before the Patent Office is decided on its own merits and in preponderance of the evidence, amendments and arguments presented in each unique case. Decisions made in previous cases before the Office or to the higher courts are not necessarily binding to the course of prosecution. Therefore, Applicant's reliance upon *Cho* in support of their assertion that the claims adequately satisfy the enabling requirement of 35 U.S.C. 112, first paragraph, with regard to the prevention of hypertension combined with hyperlipidemia or atherosclerosis, asthma, bronchitis, interstitial lung disease, type 2 diabetes mellitus, prediabetes, metabolic syndrome, insulin resistance or hypertensive insulin resistance has been considered, but is not persuasive. This case involved a distinctly different fact pattern from the present case and, therefore, cannot be relied upon to direct the decisions made during prosecution of the present application.

However, even if *Cho* was relevant to the present claims, the issue at hand is that Applicant has

failed to provide the skilled artisan with any direction or criteria as to how the population of patients in need of prevention would have been determined in the absence of clinical pathology (i.e., prior to the development of signs or symptoms associated with the claimed conditions) without requiring an undue level of experimentation. Accordingly, while *Cho* concludes that compounds or combinations with activity in treating a condition would necessarily be effective in preventing the same as long as they were administered before the onset of the condition, the skilled artisan would have required sufficient direction as to how such patients would be identified in the absence of clear and obvious clinical pathology *so that* such compound could be administered prior to onset and, thus, *prevent* the condition from developing. In the absence of such direction, the skilled artisan would have no alternative recourse but the burden of executing an undue level of experimentation in order to determine those patients in need of prevention of the claimed diseases.

For these reasons, and those set forth at pages 4-14 of the previous Office Action dated March 30, 2006, rejection of claims 1-17 remains proper and is **maintained**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 18-32 remain rejected under 35 U.S.C. 102(b) as being anticipated by De Gasparo et al. (WO 01/76573; 2001) in light of Robl et al. (U.S. Patent Application Publication No. 2002/0013334; January 31, 2002), cited to show a fact, each already of record, for the reasons of record set forth at pages 14-16 of the previous Office Action dated March 30, 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the rejection on the grounds that De Gasparo et al. does not specifically disclose the combination of telmisartan and simvastatin anywhere and, therefore, the Examiner has not pointed out how the reference anticipates the claims.

Applicant's traversal has been carefully considered in its entirety, but fails to be persuasive.

Please reference pages 14-16 of the previous Office Action dated March 30, 2006, which sets forth the teachings of De Gasparo et al. insofar as the reference expressly teaches the combination of an AT1-receptor antagonist in combination with an HMG-CoA reductase inhibitor (page 1, lines 27-29), wherein the AT1-receptor antagonist is selected from telmisartan (page 3, line 22) and the HMG-CoA reductase inhibitor is selected from simvastatin (page 5, lines 9-11). De Gasparo et al. clearly contemplates embodiments of the invention wherein the combination of at least two therapeutic components comprises an AT1-receptor antagonist (of which telmisartan is expressly disclosed) or a pharmaceutically acceptable salt thereof, and an HMG-CoA reductase inhibitor (of which simvastatin is expressly disclosed) or a pharmaceutically acceptable salt thereof. Please reference page 1, line 22 of page 3 and lines 9-11 of page 5 of De Gasparo et al. This teaching is clear, exact and unequivocally speaks to the contrary of Applicant's traversal that the reference does not disclose the claimed combination.

For these reasons, rejection of claims 1, 8 and 18-32 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 8-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over De Gasparo et al. (WO 01/76573; 2001) in light of Robl et al. (U.S. Patent Application Publication No. 2002/001334; January 31, 2002), cited to show a fact, in view of Cecil's Textbook of Medicine (2000), Harlan et al. (U.S. Patent Application Publication No. 2001/0006656; July 2001) and Bohm et al. (WO 02/15891; February 2002), each already of record, for the reasons of record set forth at pages 16-22 of the previous Office Action dated March 30, 2006, of which said reasons are herein incorporated by reference.

Applicant states in the remarks that claims 1-20 were rejected under 35 U.S.C. 103(a). This is not correct. Please reference page 17 of the Office Action dated March 30, 2006, which set forth previously presented claims 1-35 as rejected under 35 U.S.C. 103(a).

Applicant traverses the rejection on the grounds that De Gasparo et al. does not disclose the specific combination of telmisartan and simvastatin anywhere and that the secondary references, i.e., Robl et al., Cecil's Textbook of Medicine, Harlan et al. or Bohm et al., do not provide motivation, reasonable expectation of success, or a teaching or suggestion of all of the claim limitations of the invention. Applicant further submits that neither the primary nor the secondary references teach or suggest that telmisartan increases the expression of genes regulated by the PPAR-gamma receptor, which is the reason that telmisartan is a preferred combination partner for simvastatin in the treatment of, e.g., diabetes.

Applicant's traversal has been carefully considered in its entirety, but fails to be persuasive.

As previously stated *supra*, Applicant's attention is directed to pages 17-18 of the previous Office Action dated March 30, 2006, which sets forth the teachings of De Gasparo et al. insofar as the reference expressly teaches the combination of an AT1-receptor antagonist in combination with an HMG-CoA reductase inhibitor (page 1, lines 27-29), wherein the AT1-receptor antagonist is selected from telmisartan (page 3, line 22) and the HMG-CoA reductase inhibitor is selected from simvastatin (page 5, lines 9-11). De Gasparo et al. clearly contemplates embodiments of the invention wherein the combination of at least two therapeutic components comprises an AT1-receptor antagonist (of which telmisartan is expressly disclosed) or a pharmaceutically acceptable salt thereof, and an HMG-CoA reductase inhibitor (of which simvastatin is expressly disclosed) or a pharmaceutically acceptable salt thereof. Please reference page 1, line 22 of page 3 and lines 9-11 of page 5 of De Gasparo et al. This teaching is clear, exact and unequivocally speaks to the contrary of Applicant's traversal that the reference does not disclose the claimed combination.

Applicant has presented the blanket statement that, "...nor does Robl et al., Cecil's Textbook of Medicine, Harlan et al. nor Bohm et al. provide what De Gasparo et al. lacks in providing a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention". Please see page 7 of Applicant's remarks. This statement of traversal is acknowledged and noted. However, the record clearly indicates that one of ordinary skill in the art would have been motivated to combine the cited references in such a manner to render the presently claimed invention *prima facie* obvious with a reasonable expectation of success in making such a combination, absent factual evidence or argument to the contrary. Applicant's attention is directed to pages 16-22 of the rejection presented in the previous Office Action dated March 30, 2006. The rejection and the reasoning set forth will not be repeated herein so as not to burden the record.

Additionally, Applicant is reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Accordingly, focusing solely on the discrete teachings of each of the cited

references is not persuasive in establishing non-obviousness because it is the combined teachings as a whole that are the basis for a proper conclusion of obviousness. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. To properly conclude obviousness of an invention does not require the claimed invention to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test in what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant further attempts to demonstrate a patentable distinction of the claimed invention over that of the prior art by submitting that neither the primary nor the secondary references teach or suggest that telmisartan increases the expression of genes regulated by the PPAR-gamma receptor, which is the reason that telmisartan is a preferred combination partner for simvastatin in the treatment of, e.g., diabetes. However, the fact that Applicant has recognized another advantage of the combination of telmisartan and simvastatin when the prior art already acknowledges the desirability of this same combination for the identical therapeutic objectives as presently claimed cannot be the basis for patentability. Please reference *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In the instant case, even if De Gasparo et al. did not recognize the advantageous effect on increasing expression of genes regulated by PPAR-gamma when telmisartan and simvastatin were combined, the fact that Applicant has recognized this advantage is not considered a new therapeutic application because the known treatment of the same diseases as presently claimed using this combination of active agents was already known and recognized in the prior art. Though mechanisms of action of chemical entities are no doubt important contributions to scientific and pharmaceutical development, the assessment of

patentability under 35 U.S.C. 103 is based upon the therapeutic applications and effects of the compounds, not the mechanism by which they exert such a therapeutic effect.

For these reasons, and those set forth at pages 16-22 of the previous Office Action dated March 30, 2006, rejection of claims 1 and 8-35 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 8-35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 2 and 7-18 of U.S. Patent Application No. 10/757,295, in view of Harlan et al. (U.S. Patent Application Publication No. 2001/0006656; 2001), each already of record, for the reasons of record set forth at pages 22-24 of the previous Office Action dated March 30, 2006, of which said reasons are herein incorporated by reference.

Applicant states that a Terminal Disclaimer will be filed should the instant claims be found otherwise allowable and that Applicant determines that U.S. Patent Application No. 10/757,295 poses a double patenting issue at that time.

Insofar as the instant claims are not in condition for allowance, and further that the instant claims and the copending claims raise an issue under the judicially created doctrine of obviousness-type double

patenting for the reasons already presented at pages 22-24 of the Office Action dated March 30, 2006, provisional rejection of claims1 and 8-35 remains proper and is **maintained**.

Claims 1, 9-13 and 18-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10, 12-15, 18 and newly added claims 19-25 of U.S. Patent Application No. 10/899,784.

Newly added claims 19-25 of U.S. Patent Application No. 10/899,784 are properly included in the present rejection over instant claims 27-35 because the copending claims further define the use of a diuretic compound (i.e., HCTZ or chlorothalidone) in an amount of 10-50 mg within the pharmaceutical composition of telmisartan and a second component, such as an HMG-CoA reductase inhibitor. The present claims clearly provide for a pharmaceutical composition comprising telmisartan and simvastatin, which may further comprise a diuretic, such as 10-50 mg of hydrochlorothiazide or 10-50 mg of chlorothalidone (see instant claims 17-18), which clearly renders obvious the pharmaceutical combination of telmisartan, an HMG-CoA reductase inhibitor and a diuretic because the teaching of simvastatin, a species of HMG-CoA reductase inhibitor, anticipates the genus of HMG-CoA reductase inhibitor(s) as a component of the pharmaceutical composition.

Applicant traverses the rejection, stating that, "the Examiner states that 'a species will always anticipate a claim to a genus'. This rule, however, does not mean that a genus [U.S.S.N. 10/899,784] always anticipates or renders obvious a species [the instant application] and the Examiner's logic is fallacious and improper."

Applicant's traversal has been carefully considered, but fails to be persuasive.

In particular, it is noted that the '784 application is later-filed than the instant application. Accordingly, the MPEP teaches that, "If the application at issue is the later filed application or both are filed on the same day, ***only a one-way determination of obviousness*** is needed in resolving the issue of

double patenting, i.e., whether the invention defined in a claim in the application would have been anticipated by, or an obvious variation of, the invention defined in a claim in the patent. See, e.g., *In re Berg*, 140 F.3d 1438, 46 USPQ2d 1226 (Fed. Cir. 1998) (the court applied a one-way test where both applications were filed the same day). ***If a claimed invention in the application would have been obvious over a claimed invention in the patent, there would be an unjustified timewise extension of the patent and an obvious-type double patenting rejection is proper.***" (emphasis added) Please reference MPEP §804.

In light of such direction, it is clear that Applicant's argument that a genus does not always anticipate or render obvious a species is not persuasive in establishing error in the propriety of the rejection because the earlier-filed application (the '015 application) teaches the species of simvastatin, which anticipates or renders obvious the genus of HMG-CoA reductase inhibitors of the later-filed application (the '784 application). There need not be a showing of two-way obviousness for the rejection to be proper. Consequently, Applicant's assertion that the Examiner's logic is fallacious and improper is not a point well taken by the Examiner.

For these reasons, and those set forth at pages 24-26 of the previous Office Action dated March 30, 2006, provisional rejection of claims 1, 9-13 and 18-35 remains proper and is **maintained**.

Claims 1, 8, 14-19 and 21-35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21 of U.S. Patent No. 11/300,947 in view of Drug Facts and Comparisons (1996), each already of record, for the reasons of record set forth at pages 26-27 of the previous Office Action dated March 31, 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the rejection on the grounds that the '947 claims the combination of telmisartan and HCTZ and does not incorporate a statin compound.

Applicant's traversal has been carefully considered, but fails to be persuasive.

First, it is noted that, with regard to the method claims, though the instant claims are directed to the administration of telmisartan and simvastatin, while the copending claims are directed to the administration of telmisartan and a diuretic, one of skill in the art would have been motivated to concomitantly administer a diuretic in combination with the telmisartan/simvastatin combination instantly claimed for the treatment of hypertension because each was known to be useful for the same therapeutic purpose. Please see page 27 of the previous Office Action. Furthermore, it is noted that the copending claims do not preclude the presence of additional components, such as a statin compound, due to the use of open transitional language, i.e., "comprising".

Second, it is noted that, with regard to the composition claims, the instant claims clearly provide for a composition comprising telmisartan, simvastatin and a diuretic. This clearly anticipates a composition comprising telmisartan and a diuretic as claimed in the copending claims. Though the copending claims do not recite a statin compound, it is noted that the copending claims do not preclude the presence of additional components, such as a statin compound, due to the use of open transitional language, i.e., "comprising".

Additionally, as stated *supra*, "If the application at issue is the later filed application or both are filed on the same day, ***only a one-way determination of obviousness*** is needed in resolving the issue of double patenting, i.e., whether the invention defined in a claim in the application would have been anticipated by, or an obvious variation of, the invention defined in a claim in the patent. See, e.g., *In re Berg*, 140 F.3d 1438, 46 USPQ2d 1226 (Fed. Cir. 1998) (the court applied a one-way test where both applications were filed the same day). ***If a claimed invention in the application would have been obvious over a claimed invention in the patent, there would be an unjustified timewise extension of the patent and an obvious-type double patenting rejection is proper.***" (emphasis added) Please reference MPEP §804.

For these reasons, and those set forth at pages 26-27 of the previous Office Action dated March 30, 2006, provisional rejection of claims 1, 8, 14-19 and 21-35 remains proper and is **maintained**.

Conclusion

Rejection of claims 1 and 8-35 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

November 16, 2006

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER